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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/856,274	05/18/2001	Sulayman D. Dib-Hajj		5193

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EXAMINER	
PAK, MICHAEL D	

ART UNIT	PAPER NUMBER
1646	

DATE MAILED: 11/28/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/856,274	DIB-HAJJ ET AL.	
	Examiner	Art Unit	
	Michael Pak	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 September 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *20-31,35,36 and 40-44* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *20-31, 35-36, 40-44* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

1. The amendment filed September 7, 2006 has been entered. Claims 20-31, 34-36, and 40-44 are examined below.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. Applicant's arguments filed September 7, 2005, have been fully considered but they are not found persuasive.

Claim Rejections - 35 USC § 102

4. Claims 20-31, 35-36 and 40-44 are rejected under 35 U.S.C. 102(e) as being anticipated by Williams (US 5,731,284) with evidence by Mayer et al. (US 5,352,683).

The reason for the rejection has been set forth in the previous office action.

Williams teaches the method of administering GDNF in an amount effective to treat neural injury (columns 16-18). Williams teach that GDNF is useful for the treatment of nerve damage and recites Alzheimer's disease as a cause of nerve damage.(column 5, line 10). Furthermore, Williams teaches that neurotrophic factors are useful for treating the degeneration of nerve cells and loss of differentiated function that results from many different types of nerve damage including physical injury, damage due to ischemia, neurotoxins, neuropathy due to chronic metabolic diseases such as diabetes, and

neurodegenerative diseases such as Parkinson's, Alzheimer's diseases and Amyotrophic Lateral Sclerosis (column 1, lines 12-33). The GDNF administration inherently affects sodium channel. The treatment with GDNF inherently alleviate the pain. The GDNF administration inherently affect the sodium channel current flow or expression. The administered GDNF of Williams will inherently affect the dorsal root ganglia or trigeminal neurons which are present in the adminstered animal or person. The sodium channels in the administered mammal inherently binds the lectin.

Mayer et al. provide evidence that neuropathic pain is due to damage to peripheral nerves or to central nervous system (column 1). Mayer et al. teach that metabolic disorders such as diabetes may be related to abnormal functioning of the pain related regions of the nervous system (column 1).

Applicants argue that administered GDNF would not inherently treat pain. However, GDNF is administered and would inherently on the neuropathic pain associated with diabetes or other metabolic disease or neurotoxins.

5. Claims 20-31, 34-36 and 44 are rejected under 35 U.S.C. 102(e) as being anticipated by Lin et al. (WO 93/06116) with evidence by Mayer et al. (US 5,352,683).

The reason for the rejection has been set forth in the previous office action.

Lin et al. teach treatment by administering GDNF for nerve damage due to diabetes and Parkinson's disease (pages 3-4, 37-42 and 106-109).

The GDNF administration inherently affects sodium channel. The treatment with GDNF inherently alleviate the pain. The GDNF administration inherently affect the sodium

channel current flow or expression. The administered GDNF of Williams will inherently affect the dorsal root ganglia or trigeminal neurons which are present in the adminstered animal or person. The sodium channels in the administered mammal inherently binds the lectin.

Mayer et al. provide evidence that neuropathic pain is due to damage to peripheral nerves or to central nervous system (column 1). Mayer et al. teach that metabolic disorders such as diabetes may be related to abnormal functioning of the pain related regions of the nervous system (column 1).

Applicants argue that administered GDNF would not inherently treat pain. However, GDNF is administered and would inherently on the neuropathic pain associated with diabetes or other metabolic disease or neurotoxins.

6. Claims 20-31, 34-36 and 40-44 are rejected under 35 U.S.C. 102(e) as being anticipated by Yan et al. (US 5,641,749) with evidence by Mayer et al. (US 5,352,683).

The reason for the rejection has been set forth in the previous office action.

Yan et al. teach the treatment of retinal ganglion cell injury such as glaucoma, physical injury, ischemia, neurotoxin, metabolic diseases such as diabetes, and neurodegerative diseases such as Parkinson's using GDNF (columns 1-5,14-20 and 25-6). Yan et al. teach that glaucoma can be characterized by painful eye (column 3, line 39). Yan et al. disclose the dosage of 1 ug/kg/day of GDNF administration (columns 4-5).

Mayer et al. provide evidence that neuropathic pain is due to damage to peripheral nerves or to central nervous system (column 1). Mayer et al. teach that metabolic disorders such as diabetes may be related to abnormal functioning of the pain related regions of the nervous system (column 1).

Applicants argue that administered GDNF would not inherently treat pain. However, GDNF is administered and would inherently on the neuropathic pain associated with diabetes or other metabolic disease or neurotoxins.

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

8. No claims are allowed.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Pak whose telephone number is 571-272-0879. The examiner can normally be reached from 8:30 to 2:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol, can be reached on 571-272-0835. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Michael D. Pak

Michael Pak
Primary Patent Examiner
Art Unit 1646
20 November 2006